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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,131	11/10/2000	Ronald B. Gartenhaus	D9498-00004	4043

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DUANE MORRIS, LLP
IP DEPARTMENT
30 SOUTH 17TH STREET
PHILADELPHIA, PA 19103-4196

EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/709,131	GARTENHAUS, RONALD B.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-17,32,36,37 and 40-48* is/are pending in the application.

4a) Of the above claim(s) *14-17 and 42-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32, 36, 37, 40, 41 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: **Gartenhaus**

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/5/2008 has been entered.

2. Claims 14-17, 32, 36, 37 and 40-48 are pending. New claim 48 has been added. Claims 1-13, 18-31, 33-35 and 38-39 have been cancelled. Claims 14-17 and 42-47 have been withdrawn from further consideration. Claim 32 has been amended.

3. Claims 32, 36, 37, 40, 41 and 48 are under examination.

Rejections Withdrawn

4. The rejection of claim 33 under 35 USC 112, first paragraph as failing to comply with the written description requirement is withdrawn in view of applicant's cancellation of the claim.

5. The rejection of claim 34 under 35 USC 112, first paragraph as failing to comply with the written description requirement is withdrawn in view of applicant's cancellation of the claim.

6. The rejection of claim 35 under 35 USC 112, first paragraph as failing to comply with the written description requirement is withdrawn in view of applicant's cancellation of the claim.

Rejections Maintained and Response to Arguments

Claim Rejections - 35 USC 101

7. The rejection of claims 32, 36, 37, 40, 41 and new claim 48 under 35 USC 101 because the claimed invention lacks patentable utility is maintained.

The response states that the published references by Levenson et al. and by Hsu et al. demonstrate the significance of MCT-1 protein. The response states that in view of the significance disclosed in the specification for MCT-1 (and subsequently confirmed by others, such as the authors of the Levenson and Hsu references), a skilled artisan would recognize the usefulness (i.e., utility) of an antibody that specifically binds with MCT-1 protein. The response states that the specification at page 6, lines 17-19, indicates that MCT-1 is overexpressed in T-cell tumor cells, and that MCT-1 protein can be detected using antibodies that bind specifically with MCT-1 (see also page 47, lines 9-23, and the paragraph bridging pages 49 and 50), and these disclosures in the specification demonstrate a specific, substantial, and credible utility for the anti-MCT-1 antibodies that are presently claimed.

Applicant's arguments have been carefully considered but are not persuasive. As indicated in the previous office action mailed on 4/4/2007, in order to satisfy the requirements of 35 USC 101, an invention must be found to have utility at the time of

filing, see MPEP 2107.01. "[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." Fisher, 421 F.3d at 1371, 76 USPQ2d at 1230. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities (see MPEP 2107.01). Thus, the Levenson and Hsu references, published in 2005 and 2003, respectively (7 and 5 years after the priority date of the instant application), can not be used to show the utility of the claimed antibody.

The specification asserts that the MCT-1 can be used for diagnosis of tumor by comparing MCT-1 expression in a tumor cell and MCT-1 expression in a non-tumor cell, wherein a difference in expression is indicative that the cell is a tumor cell (paragraph bridging pages 4-5). The specification discloses that MCT-1 gene is amplified in the HUT 78 cell line and that in NIH 3T3 cells transfected with a MCT-1 construct, which constitutively expressed MCT-1 protein, the G1 phase of the cell cycle was shortened and promotes anchorage independent growth. However, when primary cancer samples were assayed from 40 CTCL patients and 20 chronic lymphocytic leukemia patients, MCT-1 amplification was not detected in any of these primary cancer samples (see page 40, lines 14-23). Furthermore as indicated in the previous office action mailed on 8/7/06, the art recognizes that the characteristics of cultured cell lines generally differ significantly from the characteristics of the primary tumor. Even though the instant

inventors found MCT-1 gene to be amplified in a cultured cell line (HUT78 cell line) with concomitant overexpression of protein, Pollack et al (Nature Genetics, 1999, 23:41-46) specifically teaches that in an assay of 3195 genes it was found that most genes in cancer cells are not either amplified or overexpressed (see Figure 5, page 44) and that most highly expressed genes are not amplified, and not all amplified genes are highly expressed (p. 45, col 1). Therefore, the mere observation of MCT-1 amplification in a single cell line i.e. HUT78 cell line (obtained from a patient afflicted with Sezary syndrome) would not be considered sufficient for establishing a correlation between MCT-1 protein expression and tumor presence. Thus, the polypeptides to which the claimed antibody binds do not have substantial utility because additional work must be done to determine whether MCT-1 protein is differentially expressed in primary cancer tissue compared to control in order to determine whether the polypeptide to which the claimed antibody binds is useful for the diagnosis of cancer. Since the asserted utility of the claimed antibody is for assaying for or identifying the polypeptide of SEQ ID NO:8, since the polypeptide of SEQ ID NO:8 does not have substantial utility for the reasons set forth above, the claimed antibody also does not have substantial utility.

Because of these reasons, the rejection is deemed proper and therefore maintained.

8. The rejection of claims 32, 36, 37, 40, 41 and 48 under 35 USC 112, first paragraph as failing to comply with the enablement requirement is maintained.

This rejection is maintained for the same reasons as set forth above for 35 USC 101 rejection.

New Grounds of Objections and Rejections

Claim Objections

9. Claims 32, 36, 37, 40 and 41 are objected to because of the following informalities:

Claims 32, 36, 37, 40 and 41 are objected to for the recitation of the term MCT-1 as the sole means of identifying the polypeptide to which the claimed antibody binds. The use of laboratory designations only to identify a particular polypeptide renders the claims unclear because different laboratories may use the same laboratory designations to define completely distinct polypeptides. For example, MCT-1 has been used in the art for designating monocarboxylate transporter 1 (see Baker et al., J. Appl. Physiol., 1998, 84: 987-997, abstract), and Metacept-1 (see Cakarovski et al., Int. J. Cancer, 2004, 110:610-616, abstract). Amendment of the claims to include a unique identifier, such as a sequence number (SEQ ID NO), which unambiguously defines the polypeptide to which the claimed antibody binds, is required.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 32, 37 and 48 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter

Claims 32, 37 and 48, as written, do not sufficiently distinguish over antibodies as they exists naturally because claims do not particularly point out any non-naturally occurring differences between the claimed antibodies and the naturally occurring antibodies. In the absence of the hand of man, the naturally occurring antibodies are considered non-statutory subject matter (Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980)). It should be noted that the mere purity of a naturally occurring product does not necessarily impart patentability (Ex parte Siddiqui, 156 U.S.P.Q. 426 (1966)). However, when purification results in a new utility, patentability is considered (Merck Co. v. Chase Chemical Co., 273 F.Supp 68 (1967), 155 USPQ 139, (District Court, New Jersey, 1967)). Amendment of the claims to recite "an isolated" or "purified" antibody or similar language would obviate this rejection.

Claim Rejections - 35 USC § 112, 1st paragraph

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection.

Applicant's amendment to the claims filed on 12/27/2005 added new claims 40 and 41. Claims 40 and 41 were amended on 2/9/07. The amended claim 40 is drawn to a composition comprising the antibody of claim 32 and a pharmaceutical acceptable carrier. The amended claim 41 is drawn to a kit comprising the composition of claim 40 and a reagent for detecting the antibody. Both claims 40 and 41 are considered new matter since the specification, drawings and claims as filed fail to disclose a composition comprising an antibody and a kit comprising said composition. The specification only discloses a composition comprising either or both of an isolated nucleic acid of the invention and an isolated polypeptide of the invention (see page 20, last paragraph), and a kit comprising said composition (see page 33). There is no clear support for a composition comprising an antibody and a pharmaceutical acceptable carrier, and a kit comprising the antibody composition and a reagent for detecting the antibody.

If applicant believes that support for the above-mentioned phrases or terms is present in the specification, claims or drawing as originally filed, applicant must, in responding to this action, point out with particularity, where such support may be found.

Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643
7/24/08